## REMARKS

The fee for a one month extension of time and any other fees that may be due in connection with the filing of this paper or with this application should be charged to Deposit Account No. 02-1818. If a Petition for extension of time is needed, this paper is to be considered such Petition. A supplemental Information Disclosure Statement accompanies this response.

Claims 1-18 and 34-39 are pending. Claim 1 is amended for clarity. No new matter is added.

**REJECTION OF CLAIMS 1-7 AND 39 UNDER 35 U.S.C. § 102(b) – Wolf *et al.***

Claims 1-7 and 39 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wolf *et al.* (WO 01/67895). The Examiner alleges that Wolfs *et al.* discloses an unflavored liquid nutritional that includes 4.607 kg fructooligosaccharides, 2.4 kg magnesium chloride, 1.18 kg sodium citrate, 1.146 kg potassium citrate and 1.134 kg sodium hydroxide (Table 6). The Examiner alleges that this disclosure meets every limitation of claims 1-7 and 39. The rejection respectfully is traversed.

## RELEVANT LAW

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Spada*, 15 USPQ2d 1655 (Fed. Cir, 1990), *In re Bond*, 15 USPQ 1566 (Fed. Cir. 1990), *Soundscriber Corp. v. U.S.*, 360 F.2d 954, 148 USPQ 298, 301, adopted 149 USPQ 640 (Ct. Cl.) 1966. See, also, *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir.), cert. denied, 110 S.Ct. 154 (1989). "[A]ll limitations in the claims must be found in the reference, since the claims measure the invention." *In re Lang*, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). It is incumbent on Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. *Lindemann Maschinen-fabrik Gmbh v. American Hoist and Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

## THE CLAIMS

Claim 1 recites a composition for use in a purgative, the composition including at least one water-soluble sodium salt; at least one water-soluble minimally degradable sugar, wherein the weight of the water-soluble minimally degradable sugar in the composition is from about 1 to about 3 times the weight of sodium salt in the composition; at least one water-soluble potassium salt, wherein the weight of the water-soluble potassium salt in the composition is from about 0.05 to about 1 times the weight of the sodium salt in the composition; and at least one water-soluble magnesium salt, wherein the weight of magnesium salt in the composition is

from about 0.1 to about 10 times the weight of sodium salt in the composition. Claims 2-7 and 39 ultimately depend from claim 1 and are directed to varius embodiments thereof.

**Disclosure of Wolf *et al.* and differences from the claimed subject matter**

Wolf *et al.* discloses two component carbohydrate systems for providing nutrition. The compositions include a source of fructose in combination with at least one readily digestible glucose polymer source, and optionally include nonabsorbent carbohydrates, dietary fiber and indigestible oligosaccharides. The liquid composition described in Table 6 on page 19 of Wolf *et al.* includes 39 ingredients, including 2.314 kg water-soluble sodium salt (1.18 kg sodium citrate and 1.134 kg sodium hydroxide), 2.412 kg water-soluble potassium salt (1.146 potassium citrate, 0.530 kg potassium chloride, 0.4025 kg potassium hydroxide, 0.333 kg potassium phosphate and 0.0002 kg potassium iodide), 3.428 kg water-soluble magnesium salt (2.4 kg magnesium chloride and 1.029 kg magnesium phosphate) 8.421 kg Fibersol®-2 and 4.607 kg fructooligosaccharides.

Wolf *et al.* discloses that Fibersol®-2 is a low molecular weight dextrin that is indigestible (page 13, lines 10-15). Fibersol®-2 maltodextrin is totally soluble in water (see FIBERSOL®-2 DIGESTION RESISTANT MALTODEXTRIN brochure, ADM Specialty Ingredients, third page, left col., second paragraph). Fibersol®-2 digestion-resistant maltodextrin is not absorbed by the small intestine and is passed on to the large intestine (see FIBERSOL®-2 DIGESTION RESISTANT MALTODEXTRIN brochure, ADM Specialty Ingredients, fourth page, right column). A maltodextrin is a carbohydrate obtained by the partial acid and/or enzymatic digestion of starch (see Igoe, Dictionary of Food Ingredients, 2nd ed. (1989), page 85). Hence, Fibersol®-2 maltodextrin is a water soluble carbohydrate that is resistant to digestion in the gastrointestinal tract. Thus, Fibersol®-2 digestion resistant maltodextrin is a minimally degradable sugar as defined in the instant specification (see page 7, lines 28-30, which states that a "minimally degradable sugar" is a carbohydrate moiety that is substantially resistant to endogenous digestion in the gastrointestinal tract).

The composition of Wolf *et al.* also includes fructooligosaccharides. As stated in the instant specification, fructooligosaccharides are exemplary of a minimally degradable sugar (*e.g.*, see page 7, lines 31-34). Thus, the composition described in Table 6 of Wolf *et al.* includes the minimally degradable sugars Fibersol®-2 digestion resistant maltodextrin and fructooligosaccharides. Because the composition of Wolf *et al.* includes 8.421 kg Fibersol®-2 and 4.607 kg fructooligosaccharides, the composition of Wolf *et al.* includes at least 13.028 kg of minimally degradable sugar.

The composition of Wolf *et al.* includes 2.314 kg of water-soluble sodium salt (1.18 kg sodium citrate and 1.134 kg sodium hydroxide). Hence, the weight of the minimally degradable sugar in the composition described in Wolf *et al.* is 5.63 times the weight of the sodium salt (13.028/2.314 = 5.63). Therefore, Wolf *et al.* does not disclose a composition that includes at least one water-soluble minimally degradable sugar, where the weight of the water-soluble minimally degradable sugar in the composition is from about 1 to about 3 times the weight of sodium salt in the composition.

**ANALYSIS**

Wolf *et al.* discloses a composition that includes water-soluble minimally degradable sugar (Fibersol®-2 digestion resistant maltodextrin and fructooligosaccharides), where the weight of the minimally degradable sugar in the composition is <u>5.63 times the weight of the sodium salt</u> in the composition. The instant claims require the weight of the water-soluble minimally degradable sugar in the composition to be from about 1 to about 3 times the weight of sodium salt in the composition. Thus, Wolf *et al.* does not disclose all elements as claimed. Therefore, Wolf *et al.* does not anticipate claim 1 nor any claim depending therefrom.

**REJECTION OF CLAIMS 1, 3, 5, 10 AND 11 UNDER 35 U.S.C. § 102(b) – Kawakami**

Claims 1, 3, 5, 10 and 11 are rejected under 35 U.S.C. 102(b) as anticipated by Kawakami (JP 05306221) because Kawakami allegedly discloses a composition that contains 32.3 to 35.7 gm of magnesium citrate in 900 ml of an aqueous solution of 4.8 to 5.4 mmol sodium chloride, 8.5 to 9.3 mmol potassium hydroxide and 10.7 to 2.1 gm sugars. The rejection respectfully is traversed.

**RELEVANT LAW**

The relevant law is discussed above.

**THE CLAIMS**

Claim 1 is discussed above. Claims 3, 5, 10 and 11 ultimately depend from claim 1 and are directed to various embodiments thereof.

**Disclosure of Kawakami and differences from the claimed subject matter**

A certified translation of Kawakami from Japanese to English accompanies this response. Kawakami discloses a composition that includes 32.3 to 35.7 gm of magnesium citrate in 900 ml of an aqueous solution of 4.8 to 5.4 mmol sodium chloride, 8.5 to 9.3 mmol potassium hydrate [potassium hydroxide] and 2.1 to 10.7 gram sugars (paragraph [0014]). Kawakami discloses that exemplary sugars in its formulation include sucrose, maltose, grape sugar, fructose and invert sugar (paragraph [0016]).

Kawakami does not disclose a composition that includes at least one water-soluble minimally degradable sugar. Kawakami does not disclose a composition that includes at least one water-soluble potassium salt, where the weight of the water-soluble potassium salt in the composition is from about 0.05 to about 1 times the weight of the sodium salt in the composition.

**ANALYSIS**

As a preliminary matter, the rejection as set forth on page 6 of the Office Action states that claims 1, 3, 5 and 10-11 are rejected, but on page 7, the Office Action states that "all of the limitations of claims 1, 3, 5, and 8-11 are met by Kawakami." Thus, the listing of claims on page 6 of the Action appears to be incorrect. Applicant traverses the rejection as applied to claims 1, 3, 5, and 8-11.

The instantly claimed compositions include as an element at least one water-soluble minimally degradable sugar. As discussed above, the instant specification defines a "minimally degradable sugar" as a carbohydrate moiety that is substantially resistant to endogenous digestion in the gastrointestinal tract. The composition of Kawakami includes a sugar, examples of which include sucrose, maltose, grape sugar, fructose and invert sugar. Sucrose is a disaccharide of glucose and fructose (see Igoe, Dictionary of Food Ingredients, 2nd ed. (1989), page 133). Maltose is a disaccharide of glucose (see *Id.*, page 85). Grape sugar is fructose (see Barker *et al.*, Apidologie 9(2): 111-116 (1978)). Invert sugar is a mixture of equal parts of glucose and fructose resulting from the hydrolysis of sucrose (see Igoe, Dictionary of Food Ingredients, 2nd ed. (1989), page 74). Glucose, fructose, sucrose and maltose are easily digested (see Mitchell, *The Use of Nutritive Sweeteners in Organic Food Processing Operations*, Organic Processing Magazine, January-March 2004). Thus, all of the sugars described in Kawakami are digested in the gastrointestinal tract. Hence, Kawakami does not disclose a composition that includes at least one water-soluble <u>minimally degradable sugar</u>. Therefore, Kawakami does not anticipate claim 1 nor any claim depending therefrom.

**REJECTION OF CLAIMS 2, 8, 9, 37 AND 38 UNDER 35 U.S.C. 103(a)**

Claims 2, 8, 9, 37 and 38 are rejected under 35 U.S.C. 103 (a) as allegedly being unpatentable over Kawakami (JP 05306221) in view of Frauendorfer (CA 2335713) in further view of Cockerill (US 4, 452,779). The Examiner alleges that Kawakami teaches every element of the claims except that the minimally degradable sugar is xylose, or a purgative that includes a hypertonic aqueous solution or magnesium sulfate as a water-soluble magnesium salt, but Frauendorfer and Cockerill allegedly teach the elements missing from Kawakami.

The Examiner alleges that Frauendorfer teaches xylose is a well-known adjuvant in the food industry that is suitable as a sweetening agent and has a laxative effect (page 3, paragraph 1). The Examiner alleges that Cockerill teaches that a saline cathartic or laxative component can be selected from the group comprising potassium sulfate, potassium chloride, sodium sulfate, sodium chloride, sodium phosphate, sodium tartrate, sodium citrate, magnesium sulfate, magnesium phosphate, magnesium oxide, magnesium hydroxide, magnesium tartrate and magnesium carbonate (col. 2, lines 19-25). The Examiner concludes that it would have been obvious to one of ordinary skill in the art to combine the teachings of Kawakami, Frauendorfer and Cockerill and use xylose as the minimally degradable sugar in the composition of Kawakami and to use magnesium sulfate as the water-soluble magnesium salt in a hypertonic solution. The rejection respectfully is traversed.

**Relevant Law**

For *prima facie* obviousness of claimed subject matter to be established under 35 U.S.C. §103, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). This principle of U.S. law regarding obviousness was **not** altered by the recent Supreme Court holding in KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 82 USPQ2d 1385 (2007). In KSR, the Supreme Court stated that "Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007).

The mere fact that prior art may be modified to produce the claimed product does not make the modification obvious unless the prior art suggests the desirability of the modification. In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); see, also, In re Papesch, 315 F.2d 381, 137 U.S.P.Q. 43 (CCPA 1963). Further, that which is within the capabilities of one skilled in the art is not synonymous with that which is obvious. *Ex parte Gerlach*, 212 USPQ 471 (Bd. APP. 1980). In addition, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Furthermore, the Supreme Court in KSR took the opportunity to reiterate a second long-standing principle of U.S. law: that a holding of obviousness requires the fact finder (here, the Examiner), to make explicit the analysis supporting a rejection under 35 U.S.C. 103,

stating that "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Id. at 1740-41, 82 USPQ2d at 1396 (citing In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

While the KSR Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. KSR, 127 S. Ct. at 1731. The court stated in dicta that, where there is a

> "market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try **might** show that it was obvious under § 103."

In a post-KSR decision, PharmaStem Therapeutics. Inc. v. ViaCell. Inc., 491 F.3d 1342 (Fed. Cir. 2007), the Federal Circuit stated that:

> an invention would not be invalid for obviousness if the inventor would have been motivated to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. Likewise, an invention would not be deemed obvious if all that was suggested was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

Furthermore, KSR has not overruled existing case law. See In re Papesch, (315 F.2d 381, 137 USPQ 43 (CCPA 1963)), In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991), and In re Deuel (51 F.3d 1552, 1558-59, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995)). "In cases involving new compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." Takeda v. Alphapharm, 492 F.3d 1350 (Fed. Cir. 2007).

The disclosure of the applicant cannot be used to hunt through the prior art for the claimed elements and then combine them as claimed. In re Laskowski, 871 F.2d 115, 117, 10 USPQ2d 1397, 1398 (Fed. Cir. 1989). "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome

wherein that which only the inventor taught is used against its teacher" W.L. Gore & Associates, Inc. v. Garlock Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

**The Claims**

Claim 1 is discussed above. Claims 2, 8, 9, 37 and 38 ultimately depend from claim 1 and include every limitation thereof.

**The teachings of the cited art and differences from the claimed subject matter.**

**Kawakami**

The teachings of Kawakami are discussed above. The composition of Kawakami does not include a minimally degradable sugar. Sucrose is not a minimally degradable sugar within the definition provided in the specification because it is not substantially resistant to endogenous digestion in the gastrointestinal tract. All of the exemplary sugars taught in Kawakami, including sucrose, maltose, grape sugar (fructose), fructose and invert sugar, are easily digested (see Mitchell, *The Use of Nutritive Sweeteners in Organic Food Processing Operations*, Organic Processing Magazine, January-March 2004).

Further, the instantly claimed compositions include at least one water-soluble potassium salt, where the weight of the water-soluble potassium salt in the composition is from about 0.05 to about 1 times the weight of the sodium salt in the composition. The compositions described in Kawakami include 8.5 to 9.3 mmol potassium hydroxide and 4.8 to 5.4 mmol sodium chloride. Thus, the compositions of Kawakami include a potassium salt in an amount that is from 1.57 times the weight of the sodium salt (8.5 potassium/5.4 sodium) to 1.94 times the weight of the sodium salt (9.3 potassium/4.8 sodium).

Hence, the composition of Kawakami does not include a minimally degradable sugar and the amount of potassium salt in the compositions of Kawakami is at least 50% greater than the upper recited limit for potassium in the instant claims. Therefore, Kawakami does not teach or suggest the instantly claimed composition.

**Frauendorfer (CA 2335713)**

Frauendorfer teaches delayed release oral dosage forms of polyunsaturated acids in a xylose-hardened gelatin capsule. Frauendorfer teaches that ordinary gelatin capsules do not provide the delayed release characteristics of its capsules, which include xylose as a hardener (page 2, lies 6-19). Frauendorfer teaches that a heat treatment is used to cause the aldehyde functionality of the xylose to react with the gelatin to cross-link the gelatin, thereby producing a structure that inhibits peroxidation of fatty acids so that anti-oxidants are

unnecessary (page 5, lines 1-10). Frauendorfer teaches that xylose is a sweetening agent and that xylose has a laxative effect (page 3, lines 1-3).

Frauendorfer does not teach or suggest a composition that includes at least one water-soluble sodium salt; at least one water-soluble minimally degradable sugar, wherein the weight of the water-soluble minimally degradable sugar in the composition is from about 1 to about 3 times the weight of sodium salt in the composition; at least one water-soluble potassium salt, wherein the weight of the water-soluble potassium salt in the composition is from about 0.05 to about 1 times the weight of the sodium salt in the composition; and at least one water-soluble magnesium salt, wherein the weight of magnesium salt in the composition is from about 0.1 to about 10 times the weight of sodium salt in the composition. Frauendorfer does not teach or suggest replacing a degradable sugar, such as sucrose, with a minimally degradable sugar, such as xylose. There is no mention of potassium salt in the compositions of Frauendorfer.

**Cockerill (US 4, 452,779)**

Cockerill teaches compositions for increasing the quantity and quality of the milk produced by a lactating mammal by removing excess fluids from mammary tissue (col. 1, lines 5-11). The composition includes (1) a non-toxic diuretic in an amount effective for withdrawing excess fluid from the mammary tissue into the blood and removing the fluid via the kidneys as urine; (2) a non-toxic saline cathartic in an amount effective for withdrawing fluid from mammary tissue into the intestinal tract of the lactating mammal preferably by providing a hypertonic solution in the intestine; and (3) a non-toxic irritant cathartic in an amount effective for readily emptying the contents of the intestinal tract of the lactating mammal, where the components of the composition provide a source of both potassium and magnesium in addition to sodium in amounts that maintain a normal electrolyte balance in the body fluids so as to avoid dehydration of the mammal (col. 1, line 60 through col. 2, line 8). In one embodiment, the composition includes, on a weight basis, on a weight basis, about 65 percent anhydrous sodium sulfate, about 13 percent magnesium sulfate monohydrate, about 12 percent sulfur and about 10 percent anhydrous potassium sulfate (col. 3, lines 10-15). Cockerill teaches that potassium sulfate can comprise from 10-50% of the composition.

The compositions of Cockerill do not include a minimally degradable sugar nor any sugar. Cockerill does not teach or suggest including a minimally degradable sugar, such as xylitol, in its formulations. Cockerill does not teach or suggest replacing a degradable sugar, such as sucrose, with a minimally degradable sugar, such as xylose.

**ANALYSIS**

Kawakami does not teach or suggest a composition that includes a <u>minimally degradable</u> sugar. The sugars in Kawakami, including sucrose, maltose, grape sugar (fructose), fructose and invert sugar, are easily digested (see Mitchell, *The Use of Nutritive Sweeteners in Organic Food Processing Operations*, Organic Processing Magazine, January-March 2004). In addition, the amount of potassium salt in the compositions of Kawakami is at least 50% greater than the upper recited limit for potassium in the instant claims.

Frauendorfer does not cure the deficiencies in the teaching of Kawakami. Frauendorfer teaches a xylose cross-linked gelatin delayed release capsule. Frauendorfer teaches that gelatin cross-linked with xylose produces a structure that inhibits peroxidation of fatty acids. Frauendorfer does not teach or suggest replacing a degradable sugar, such as sucrose, in the compositions of Kawakami, with a minimally degradable sugar, such as xylose. Thus, the combination of the teaching of Kawakami and Frauendorfer does not result in a composition that includes a minimally degradable sugar as instantly claimed. Further, the compositions of Frauendorfer are completely different from the compositions of Kawakami and are for completely different purposes.

In addition, the amount of potassium salt in the compositions of Kawakami is at least 50% greater than the upper recited limit for potassium in the instant claims. There is no mention of potassium salt in the teachings of Frauendorfer. Hence, there can be no teaching or suggestion in Frauendorfer with respect to reducing the amount of potassium salt in an intestinal tract lavage composition such as taught by Kawakami to achieve a level of potassium salt as recited in the instant claims. Thus, the combination of the teaching of Kawakami and Frauendorfer does not result in a composition that includes potassium salt in a ratio to sodium salt as instantly claimed. Therefore, the combination of the teachings of Kawakami and Frauendorfer does not result in every element of the claimed subject matter.

Cockerill does not cure the deficiencies in the combination of the teachings of Kawakami and Frauendorfer. Cockerill teaches a dry powdered composition that is mixed with the feed of a lactating mammal, where the composition includes 65% sodium sulfate, 13% magnesium sulfate, 10% potassium sulfate and 12% sulfur. None of the formulations of Cockerill includes a minimally degradable sugar nor any sugar. Cockerill does not teach or suggest anything with respect to a minimally degradable sugar, such as xylose, nor suggest that xylose can be used to replace sucrose in a composition, such as the composition of Kawakami. Hence, Cockerill does not teach or suggest replacing the *sucrose or degradable sugar* in the

composition of Kawakami with a minimally degradable sugar, such as xylose. Thus, Cockerill does not teach or suggest elements of the instantly claimed compositions that are missing from the combination of the teachings of Kawakami and Frauendorfer. Neither Frauendorfer nor Cockerill nor their combination teaches or suggests replacing the sucrose of Kawakami with a minimally degradable sugar, such as xylitol, nor reducing the amount of potassium of the composition of Kawakami to achieve the ratio of potassium salt based on sodium salt in the composition as instantly claimed.

None of Kawakami, Frauendorfer and Cockerill, alone or in any combination, teaches or suggests a composition that includes as elements at least one water-soluble sodium salt; at least one water-soluble minimally degradable sugar, where the weight of the water-soluble minimally degradable sugar in the composition is from about 1 to about 3 times the weight of sodium salt in the composition; at least one water-soluble potassium salt, where the weight of the water-soluble potassium salt in the composition is from about 0.05 to about 1 times the weight of the sodium salt in the composition; and at least one water-soluble magnesium salt, where the weight of magnesium salt in the composition is from about 0.1 to about 10 times the weight of sodium salt in the composition. Therefore, for at least these reasons, the combination of Kawakami and Frauendorfer and Cockerill does not teach or suggest every element of claim 1 nor any of claims 2, 8, 9, 37 and 38, which ultimately depend from claim 1 and include the limitations thereof. Therefore, the Examiner has failed to set forth a *prima facie* case of obviousness of any of the pending claims, including claims 1, 2, 8, 9, 37 and 38.

* * *

In view of the amendments and remarks herein, reconsideration and allowance are respectfully requested.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---|---|---|---|
| Applicant | : BORODY *et al.* | Art Unit | : 1616 |
| Serial No. | : 10/506,728 | Examiner | : Holt, Andriae M. |
| Filed | : June 27, 2005 | Confirm. No. | : 7029 |

Title : **ELECTROLYTE PURGATIVE**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

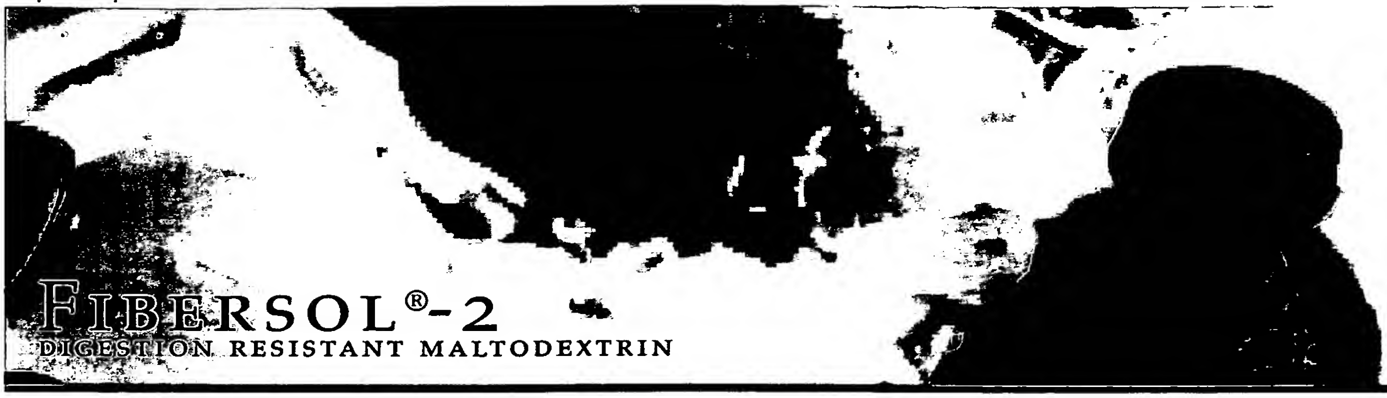
## ATTACHMENTS

1. FIBERSOL®-2 Digestion Resistant Maltodextrin (ADM brochure).

2. Igoe, Dictionary of Food Ingredients, 2nd ed. (1989), pages 55, 85 and 133).

3. Barker *et al.*, Apidologie 9(2): 111-116 (1978).

4. Mitchell, *The Use of Nutritive Sweeteners in Organic Food Processing Operations*, Organic Processing Magazine, January-March 2004.



# FIBERSOL®-2
DIGESTION RESISTANT MALTODEXTRIN

FOOD INGREDIEN

- BAKING & CEREALS
- BEVERAGES
- CANDY & CONFECTIONER
- DAIRY
- MEAT PRODUCT
- OTHER PROCES FOODS
- SNACK FOODS

## A VERSATILE FIBER FOR CONSUMERS AND FORMULATORS

FIBERSOL®-2 DIGESTION RESISTANT maltodextrin is great for consumers because it's a soluble dietary fiber that doesn't act like one. It doesn't affect the taste of foods and doesn't leave clear or transparent beverages cloudy or gritty. But its functionality isn't limited to consumers. Fibersol-2 digestion resistant maltodextrin functions for formulators too!

Fibersol-2 digestion resistant maltodextrin is multi-functional and can be used in countless applications, so it's perfect for formulators, as well as consumers. In addition to rapid dispersion, this fiber is clear or transparent in solution, highly soluble, and stable under virtually all conditions. Fibersol-2 digestion resistant maltodextrin is also a very low viscosity, low hygroscopicity, and low sweetness fiber source with water-binding and body- and texture-improving characteristics.

### WHY FIBERSOL®-2 DIGESTION RESISTANT MALTODEXTRIN?

- **Dietary fiber (90% min. DSB)**
- **High solubility**
- **Rapid dispersion**
- **Clear, transparent solution**
- **No inherent or added flavor**
- **Very low viscosity**
- **Water binding**
- **Improves body/texture**
- **Low hygroscopicity**
- **Low sweetness**
- **Acid, heat/retort, and freeze/thaw stable**

Now you can increase the dietary fiber content—and nutritional value—of practically any food, beverage, or supplement. In fact, you can meet your customers' recommended daily allowance of fiber—25 grams—by using Fibersol-2 digestion resistant maltodextrin in your applications. **And even at high levels, Fibersol-2 digestion resistant maltodextrin doesn't affect the taste or interfere with mineral or calcium absorption—so it's an excellent fiber source for consumers of any age!** Fibersol-2 digestion resistant maltodextrin can be incorporated into all types of beverages, processed foods, cultured dairy products and frozen dairy desserts, confections, dietary supplements in every form, and much more!

Meet consumers' needs for a great-tasting fiber source and your needs for an easy-to-use fiber ingredient. As with all ADM ingredients, Fibersol-2 digestion resistant maltodextrin is backed by a technical support team that understands ingredient technology and is committed to providing application solutions. You'll find more information on Fibersol-2 digestion resistant maltodextrin inside!

Fibersol-2™

*Digestion Resistant Maltodextrin*

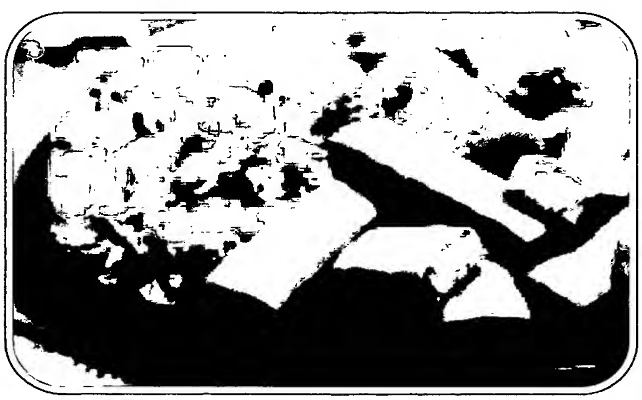
ADM

For customers around the world, ADM draws on its resources–its people, products, and market perspective–to help them meet today's consumer demands and envision tomorrow's needs.
RESOURCEFUL BY NATURE™

www.admworld.com | 800-637-5843 | specialtyingredients@admworld.com

## THE FACTS ABOUT FIBERSOL®-2 DIGESTION RESISTANT MALTODEXTRIN

Fibersol®-2 digestion resistant maltodextrin is a sprayed-dried powder produced by a proprietary method of controlled enzymatic hydrolysis. This concentrated form (90% minimum, dry weight basis) of soluble dietary fiber is considered "natural" by most industry definitions. It has been approved as GRAS (generally recognized as safe) by the Food and Drug Administration and certified kosher and pareve by the Orthodox Union.



There are a variety of functional, physical, and sensory attributes that Fibersol-2 digestion resistant maltodextrin will bring to your food and beverage applications.

## KEY APPLICATIONS

- Beverages (all types)
- Reduced-, low-, no-fat foods
- Reduced-, low-calorie foods
- Confections
- Fiber supplements and enrichments
- Baked goods
- Ready-to-eat and hot cereals
- Nutritional foods
- Snack foods
- Processed meats
- Cultured dairy foods
- Frozen dairy desserts
- Meal replacement foods
- Dietary supplements
- Spreads
- No-sugar-added foods
- Dry mixes
- Soups, sauces, dressings
- Medical foods
- High-intensity tabletop sweeteners

## A Functional Fiber in Every Way

**Soluble Dietary Fiber:** 90% minimum DSB soluble dietary fiber (in accordance with AOAC method #2001.03) and one of the most economical fiber sources available. Fibersol®-2 digestion resistant maltodextrin, analytically and nutritionally, meets the definition of dietary fiber for nutrition labeling purposes, as published by the American Association of Cereal Chemists (AACC) and proposed by the National Academy of Sciences (NAS).

**High Solubility:** Totally soluble in water up to 70% (w/w) at 20° C, allowing it to be solubilized in small amounts of water as needed.

**Rapid Dispersion:** Readily dispersible in water and highly compatible with dry drink mix applications, including simple and more complex co-dried or dry blended mixes.

**Clear, Transparent Solution:** At typical use levels, it yields clear, transparent solutions that are near water-like in performance. This allows for ultimate formulation versatility.

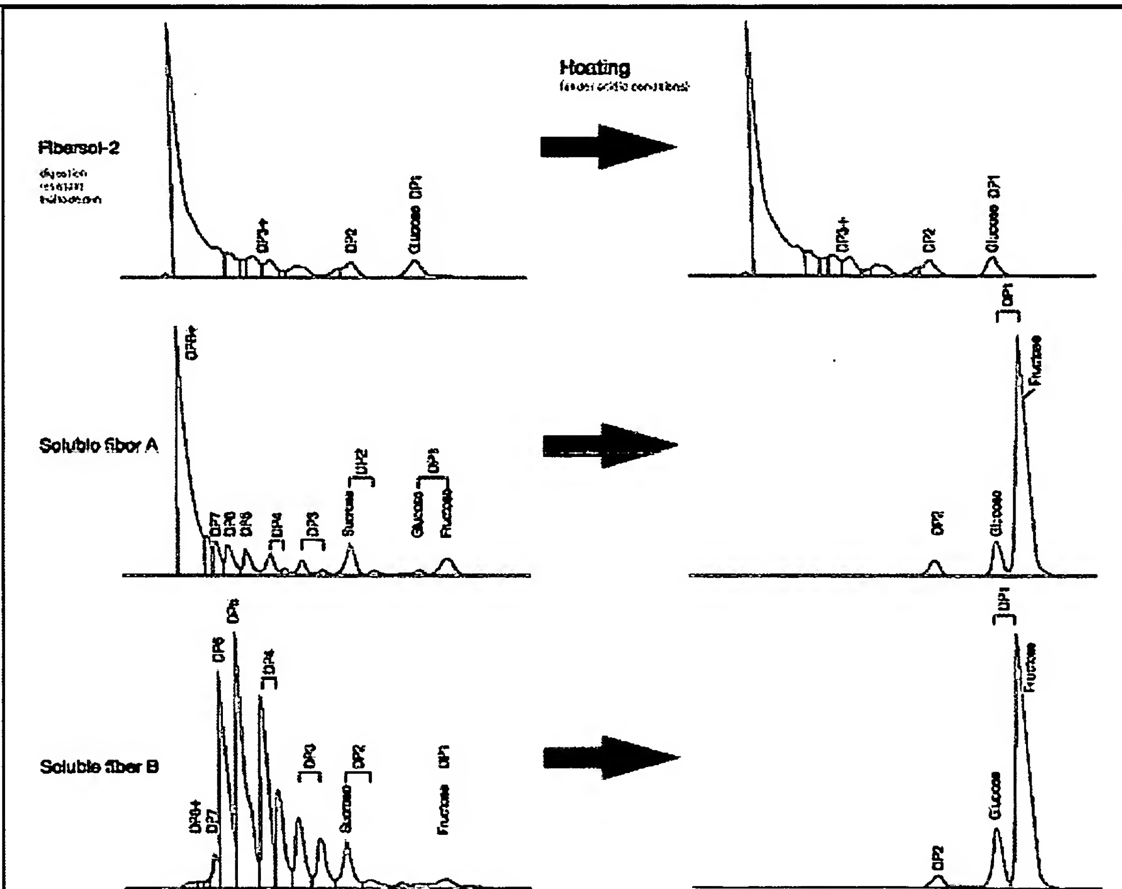
**No Inherent or Added Flavors:** Fibersol-2 digestion resistant maltodextrin adds no flavor or odor, making it suitable for use in even delicately flavored applications.

**Improves Flavor, Performance of High-Intensity Sweeteners:** Modifies and improves the sweetness and aftertaste performance of many high-intensity sweeteners, allowing for flavor, sweetness, and mouthfeel improvements to a variety of low-calorie foods.

**Low Sweetness:** Has essentially no sweetness of its own. Sweetness less than 10% of sucrose is typical. Can be used in many applications where additional sweetness is undesirable.

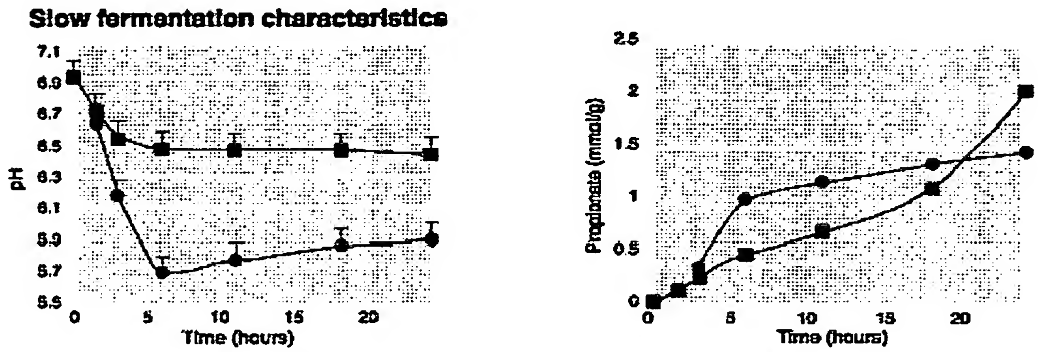
**Acid and Heat/Retort Stable:** Stability to acid and heat/retort processing—including stability in high acid, hot filled, aseptic, or retorted products like juices, sauces, puddings, fluid milks, and sports drinks—is unique. It retains its dietary fiber characteristics and function across process and post-process distribution conditions.

Acid/heat stability of Fibersol®-2 digestion resistant maltodextrin as compared to other soluble fiber sources




A 10% solution was adjusted to pH 2.4 and kept at 95° C for 60 min.
The resulting solutions were tested by HPLC, and changes from fiber to simple sugars were quantified.

In-vitro fermentation of Fibersol®-2 digestion resistant maltodextrin

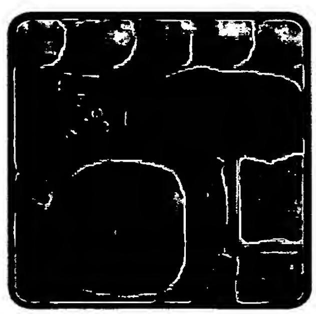



Figures. LEFT: pH values of in-vitro fermentation of Fibersol-2™ digestion resistant maltodextrin (■) and Solka's fiber B (●).
RIGHT: Propionate production of in-vitro fermentation of Fibersol-2 digestion resistant maltodextrin (■) and Solka's fiber B (●).

From "Glucose-Based Oligosaccharides Exhibit Different In-Vitro Fermentation Patterns and Affect In-Vitro Apparent Nutrient Digestibility and Microbial Population in Dogs" J. Nutr., 130, 1267-1273, 2000.

Slow Fermentation: Fibersol®-2 digestion resistant maltodextrin is fermented slowly, producing less acid and gas than most soluble dietary fibers, thus avoiding undesirable side effects to consumers.

Superior Freeze/Thaw Stability: Flavor, function, and performance of dietary fiber content are stable to repeated freezing and thawing when stressed due to distribution abuse or when used in a variety of frozen foods.



Very Low Viscosity: A precise and extremely low viscosity (15 cps, 30% solution at 30° C), allowing use rates in excess of 10% without direct impact on the mouthfeel, flavor, and other sensory performance requirements.

Low Hygroscopicity: Very low tendency to pick up moisture from the air. This makes for ease in handling and delivery to point of use, can effectively protect dry blends with other more hygroscopic ingredients.

Binds Water: Also releases bound water easily, adding perceived moistness to a variety of applications including low water activity products.

Resists Browning: Does not actively participate in non-enzymatic Maillard-type browning. Although its D.E. designation is similar to 10 D.E. maltodextrin, Fibersol-2 digestion resistant maltodextrin is more stable to non-enzymatic browning than 10 D.E. maltodextrin.

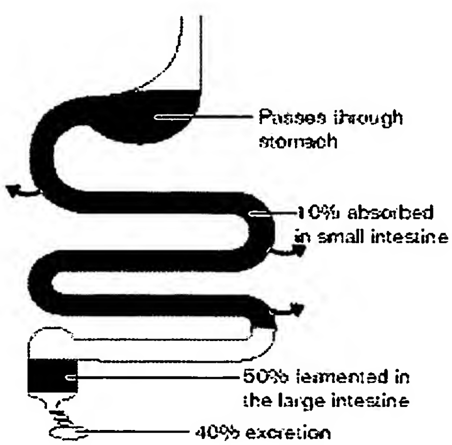
## The Science Behind Fibersol®-2 Digestion Resistant Maltodextrin

Fibersol-2 digestion resistant maltodextrin is produced by a proprietary process to purposefully rearrange cornstarch molecules to convert a portion of normal alpha -1,4- glucose linkages to random 1,2-, 1,3-, and 1,4- alpha and beta linkages. The human digestive system effectively digests only alpha -1,4- linkages. Therefore, other linkages created are resistant to digestion, so they are not absorbed in the small intestine and are passed on to the large intestine. Fibersol-2 digestion resistant maltodextrin is partially fermented in the large intestine. The fractions that aren't used are excreted.

### Nutritional Efficacy of Fibersol-2 Digestion Resistant Maltodextrin

More than 10 years of nutritional feeding studies in animals and humans worldwide as described by Ohkuma & Wakabayashi in *Advanced Dietary Fibre Technology*, 2001, have shown the direct, or indirect, impact of Fibersol-2 digestion resistant maltodextrin's bioavailability on a number of functions. Its pre-biotic effect on good intestinal health helps maintain healthful serum cholesterol, serum triglycerides, blood glucose levels, regular laxation, and levels of intestinal microflora.

As a water-soluble fiber, Fibersol®-2 digestion resistant maltodextrin can effectively promote the growth of a variety of beneficial bacteria (naturally occurring or ingested as pro-biotics) in the colon. In promoting the growth of beneficial bacteria, Fibersol-2 digestion resistant maltodextrin indirectly reduces the presence of undesirable bacterial species. Additionally, secondary and tertiary nutritional benefits from fermentation byproducts such as short chain fatty acids can add to maintaining good intestinal and overall health.




## FIBERSOL®-2 DIGESTION RESISTANT MALTODEXTRIN NUTRITIONAL INFORMATION

| *Nutrient* | *Per 100 grams of ingredient* |
|---|---|
| Total Calories | 380 Kcal |
| Calories from Fat | 0 Kcal |
| Calories from Saturated Fat | 0 Kcal |
| Total Fat | 0 g |
| Saturated Fat | 0 g |
| Polyunsaturated Fat | 0 g |
| Monounsaturated Fat | 0 g |
| Cholesterol | 0 mg |
| Sodium | 1 mg |
| Potassium | 0 mg |
| Total Carbohydrate | 95.0 g |
| Dietary Fiber | 90.0 g |
| Soluble Fiber | 90.0 g |
| Insoluble Fiber | 0 g |
| Sugars | 5.0 g |
| Sugar Alcohol | 0 g |
| Other Carbohydrate | 0 g |
| Protein | 0 g |
| Vitamin A | 0 IU |
| Vitamin C | 0 mg |
| Calcium | 0 mg |
| Iron | 0 mg |

## OTHER ESSENTIAL VITAMINS AND MINERALS (PER 100 GRAMS)

| | |
|---|---|
| Thiamine | 0 mg |
| Riboflavin | 0 mg |
| Niacin | 0 mg |
| Vitamin D | 0 IU |
| Vitamin E | 0 IU |
| Vitamin B-6 | 0 mg |
| Folic Acid | 0 mg |
| Vitamin B-12 | 0 mg |
| Phosphorus | 0.48 mg |
| Iodine | 0 mg |
| Magnesium | 0.07 mg |
| Zinc | 0 mg |
| Copper | 0.01 mg |
| Biotin | 0 mg |
| Pantothenic Acid | 0 mg |

# Technical, Labeling, and Storage

## Physical Characteristics

*Color:* Off-white powder; clear, transparent in 10% solution; resists both enzymatic and non-enzymatic browning
*Flavor:* No flavor, clean
*Solubility:* Water soluble up to 70% (w/w) at 20° C
*Dispersibility:* Excellent
*Hygroscopicity:* Very low
*Stability:* Acid, heat/retort processing, and freeze/thaw stable
*Viscosity:* Very low; 15 cps, 30% solution at 30° C
*Sweetness:* Low, no sweetness (10% of sucrose at 30% T.S.)
*Bulk density:* Approx. 0.48 g per ml (30 lbs. per cubic foot)

## Typical Chemical Properties

*Water-soluble dietary fiber*:* 90% minimum DSB (in accordance with AOAC method #2001.03)**
*Moisture:* 5% maximum
*Protein:* None
*Fat:* None
*Ash:* 0.2% maximum
*DE:* 8-12.5
*Acidity:* pH 4.0-6.0
*Calories:* 4.0 calories per g (U.S. CFR)

*Carbohydrate profile (% of total carbohydrate)*
*DP1:* 1.5%
*DP2:* 2.5%
*DP3:* 4.0%
*DP4-6:* 12.0%
*DP7+:* 80.0%

## Microbiological Properties

*Standard plate count:* Less than 300/g
*Yeast/mold:* Less than 100/g
Coliform: Negative
E. coli: Negative
Salmonella: Negative
*Coagulase positive staph:* Negative

## Ingredient Statement

Digestion Resistant Maltodextrin
Resistant Maltodextrin
Maltodextrin

These statements may be modified with (Fibersol®-2 fiber), (soluble dietary fiber), (dietary fiber), (fiber), etc.

## Packing and Storage

Fibersol-2 digestion resistant maltodextrin is packaged in 50 lb. (22.7 kg) bags and 475 kg bulk totes. Keep Fibersol-2 digestion resistant maltodextrin stored in a cool, dry place, and its shelf life can exceed 18 months.

*Fibersol-2 digestion resistant maltodextrin is a rich source of water soluble dietary fiber. This is consistent with both the American Association of Cereal Chemists' and the Food and Nutrition Committee of the National Academy of Sciences' (NAS) definitions of dietary fiber. In both cases, Fibersol-2 digestion resistant maltodextrin is classified as "resistant maltodextrin," and in both cases, "resistant maltodextrin" is classified as dietary fiber.

**In April 2001, AOAC formally approved analytical methodology ("Determination of Total Dietary Fiber and Resistant Maltodextrin in Select Foods by Combination of Enzyme-Gravimetric and LC," AOAC method #2001.03), which measures digestion resistant maltodextrin.

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Glucose-Based Oligosaccharides Exhibit Different In-Vitro Fermentation Patterns and Affect In-Vivo Apparent Nutrient Digestibility and Microbial Populations in Dogs, *J Nutrition*, **131**, 1267-1273 (2000).

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## FIBERSOL®-2 SOLUBLE FIBER

| Product | Water soluble dietary fiber[a] | Solubility | Color in solution | Certification | Characteristics | Applications |
|---|---|---|---|---|---|---|
| *Fibersol-2* | 90%* minimum** | Water, up to 70% (w/w) @ 20° C | Clear, colorless | GRAS as maltodextrin Kosher and parve by O.U. | No inherent or added flavor, high solubility, rapid dispersion, very low viscosity, low sweetness; acid, heat/retort, and freeze/thaw stable | Beverages (all types), nutritional bars, fiber supplements and enrichments, baked goods, cereals (RTE and hot), dairy foods, and dry mixes |

*Meets criteria for fiber.
**AOAC Official Method 2001.03—Total Dietary Fiber in Foods Containing Resistant Maltodextrin.

# Dictionary of Food Ingredients

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VNR VAN NOSTRAND REINHOLD
NEW YORK

Library of Congress Catalog Card Number 88-38855
ISBN 0-442-31927-4



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Printed in the United States of America

Van Nostrand Reinhold
115 Fifth Avenue
New York, New York 10003

Van Nostrand Reinhold International Company Limited
11 New Fetter Lane
London EC4P 4EE, England

Van Nostrand Reinhold
480 La Trobe Street
Melbourne, Victoria 3000, Australia

Macmillan of Canada
Division of Canada Publishing Corporation
164 Commander Boulevard
Agincourt, Ontario MIS 3C7, Canada

16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1

**Library of Congress Cataloging-in-Publication Data**

Igoe, Robert S.
Dictionary of food ingredients/Robert S. Igoe.—2nd ed.
p. cm.
Bibliography: p.
ISBN 0-442-24002-3
1. Food—Composition—Dictionaries. I. Title.
TX551.I26 1989
641.1'03'21—dc19 88-38855
CIP

# I

**Indian Gum** See **Ghatti**.

**Indigotine** See **FD&C Blue #2**.

**Instantized Flour** A flour made by a milling or agglomerating procedure which makes it readily pourable, providing convenience.

**Invert Sugar** A sweetener that is a mixture of equal weights of dextrose (glucose) and levulose (fructose). It is more soluble than sucrose and has higher moisture-retaining properties because of the fructose content. It resists crystallization. It is used in candy and icings because it is sweeter, more soluble, and crystallizes less readily than sucrose.

**Invert Sugar Syrup** A sweetener produced by an inversion process. It is produced by solubilizing sucrose in water followed by hydrolization to a mixture of dextrose and fructose using acids, invertase enzyme, or ion exchange resins to catalyze the reaction. Several invert syrups are obtained, such as medium invert consisting of 50 percent sucrose, 25 percent dextrose, 25 percent fructose, and total invert consisting of 3 to 5 percent sucrose, 48 percent dextrose, and 47 percent fructose. It has improved microbiological stability because of its high solids content and it is used in soft drinks. It is also termed sugar syrup, invert.

**Iodine** I. A halogen element extracted from Chilean nitrate-bearing earth or from seaweed. It functions by its presence in the thyroid

in yeast fermentation. It is also termed extract of malted barley and corn.

**Malt Extract** A flavorant formed by extracting the water-soluble enzymes from barley and evaporating to form a concentrate that contains D-alpha-amylase enzyme. This enzyme hydrolyzes starch to dextrin and maltose. It is used to provide malt flavor, and in conjunction with spices, seasonings, and flavors.

**Malt Flour** The flour prepared by the drying and grinding of barley or wheat sprouted under controlled conditions. It can be used as a malt supplement or converted to malt syrups. The malt functions to modify starch during initial stages of baking.

**Maltodextrin** The product obtained from the partial acid or enzymatic hydrolysis of starch, in the same manner as corn syrup except the conversion process is stopped at an earlier stage. It has a dextrose equivalent of less than 20 and basically is not sweet and is not fermentable. It has fair solubility. It functions as a bodying agent, bulking agent, texturizer, carrier, and crystallization inhibitor. It is used in crackers, puddings, and candies.

**Maltol** $C_6H_6O_3$. A flavor enhancer used as a synthetic flavoring substance, the function of which is related to ethyl maltol. It occurs naturally in chicory, cocoa, coffee, and cereals. It does not contribute a flavor of its own, but modifies the inherent flavors. As compared to ethyl maltol, it is one-half to one-sixth as effective. It is less soluble, having a solubility of 1 g in 82 ml of water at 25°C. It has a melting range of 160 to 164°C. It is used to enhance the flavor and aroma of fruit, vanilla, and chocolate-flavored foods and beverages. It is also used in beverages and desserts with a typical usage range of 10 to 200 parts per million.

**Maltose** $C_{12}H_{22}O_{11}$. A sweetener formed by the enzymatic action of yeast on starch. It consists of two dextrose molecules. Maltose dissolves and crystallizes slowly in aqueous solutions, and is less sweet and more stable than sucrose. It is used in combination with dextrose in bread and in instant foods, and is also used in pancake syrups.

**Malt Syrup** The syrup obtained from barley by extraction and evaporation of the worts to 80 to 81 percent solids. It is used as a malt flavor component, source of malt and protein, and to provide color. It is used in bakery goods such as rolls and bagels at 1 to 3 percent of the

s and vegetable fat top-
toes to allow for produc-

uccinate See **Succis-**

ing citric acid (not solu-
readily dissolves in oils,
›revents metal ions from
ıncidity. It is related to
and margarine.

led from a wheat blend,
el which equates to 100

ıd dough conditioners
noglycerides. They are
›er 45.4 kg of flour to
ł improve texture. They

nmercially prepared by
It is a nonhygroscopic
naric and adipic acid. It
it is not a substitute for
ı modifying the plastic-
: and flavor enhancer in

hydrolyzes very slowly
lity and a low melting
ı products at compara-
ıg acidulant for baking

.ed stearoyl propylene
ening to help improve



**Sucrose** See **Sugar**.

**Sugar** A sweetener that is the disaccharide sucrose, consisting of one molecule of glucose and one molecule of fructose. It is obtained as cane or beet sugar. It has relatively constant solubility and is a universal sweetener because of its intense sweetness and solubility. It is available in various forms which include granulated, brown, and powdered. It is used in desserts, beverages, cakes, ice cream, icings, cereals, and baked goods. It is also termed beet sugar, cane sugar, and sucrose.

**Sugar, Brown** See **Brown Sugar**.

**Sugar, Natural** See **Turbinado Sugar**.

**Sugar, Powdered** See **Powdered Sugar**.

**Sugar, Raw** A natural sugar that has been washed to remove the impurities. It has a light golden color resulting from the molasses and a larger crystal size than granulated sugar. It is used where the flavor of natural sugar is desired, such as in cookies, bread, and cakes.

**Sugar, Reducing** See **Reducing Sugar**.

**Sugar Syrup** A sweetener that is clear solutions of sucrose existing in varying grades. There is a water-white grade which is a sparkling clear syrup used in canned goods and beverages. There is also a light straw grade which has small amounts of color and nonsugar components.

**Sugar Syrup, Invert** See **Invert Sugar Syrup**.

**Sugar, Washed Raw** See **Turbinado Sugar**.

**Sulfur Dioxide** $SO_2$. A preservative, being a gas that dissolves in water to yield sulfurous acid. Sulfite salts, such as sodium and potassium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite, yield free sulfurous acid at low pH. Sulfur dioxide prevents the discoloration of foods by combining with the sugars and enzymes. It also inhibits bacterial growth. It is used in beverages, cherries, wines, and fruits.

**Sulfuric Acid** $H_2SO_4$. An acidulant that is a clear, colorless, odorless

# LABORATORY COMPARISON OF HIGH FRUCTOSE CORN SYRUP, GRAPE SYRUP, HONEY, AND SUCROSE SYRUP AS MAINTENANCE FOOD FOR CAGED HONEY BEES

*Apidologie*, 1978, **9** (2), 111-116.

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***SUMMARY***

Honey or high fructose corn syrup fed to worker bees failed to show any advantage over sucrose syrup. Grape syrup caused dysentery and reduced survival. Caged bees survived longest on sucrose syrup.

## INTRODUCTION

A commercial process utilizes glucose isomerase to convert the glucose from hydrolyzed corn starch to a mixture containing glucose and high levels of fructose (ASHENGREEN, 1975). To humans, fructose is sweeter than glucose or sucrose. Consequently, the higher the content of fructose, the lower the concentration of sugar needed to sweeten food or drinks. Thus, high fructose corn syrup is an economical sweetener for humans.

Does isomerized corn syrup provide advantages in bee foods? Its sugar composition closely resembles that of honey, but isomerized sugar may not be sweeter than sucrose to honey bees. In fact, a preference of older bees for sucrose over glucose and fructose may explain why they leave hives containing stored honey to forage for nectar. Nevertheless, beekeepers generally consider honey to be unparalleled as a bee food despite its failure to sustain worker bees as long as sucrose (BARKER and LEHNER, 1974 a, b). High fructose corn syrup offers advantages besides lower cost, such as feeding convenience. Furthermore, some beekeepers find less robbing when bees are fed high fructose corn syrup instead of sucrose syrup. This may be a consequence of lower attraction. No one sugar seems to match sucrose for acceptance or for survival value (BARKER, 1977; BARKER and LEHNER, 1974 c, d).

Fructose is sometimes called "grape sugar" because grapes contain so much of it. Pomace from crushed grapes attracts honey bees (FEO *et al.*, 1957), and sometimes bees are blamed for damage to ripe grapes. However, RADOEV (1971) found that grape juice was toxic to honey bees. We hoped that commercially available grape syrup would be attractive and

nutritious for honey bees.

Our objective was to compare sucrose syrup, honey, high fructose corn syrup, and grape syrup for sustenance of honey bees and for acceptance, comb-building, and hoarding by bees.

**MATERIALS AND METHODS**

Bees shaken from combs of brood were held in small (24 x 24 x 8 cm) cages for 24 hr. Each cage contained ca. 1,200 bees and a rack holding two wooden bars 25 cm long with a 2 x 2 cm piece of comb foundation centered on one bar. A caged queen was attached to a bar beside the foundation. After 48 hr. the bees had settled on the bars and were building comb. Then, the queen cage was moved to an end of the bar, and bees were released from the small cage into a larger (56 x 56 x 43 cm) cage.

The room with the three replicate cages of bees for each treatment was maintained at 28 ± 1 °C and 20% RH with a 3 hr photoperiod. Aluminum foil on a rack held below fluorescent ceiling lights served to reduce clustering at the top of cages when lights were on.

Dead bees were removed and counted daily for 60 days. "Bee days" were obtained by adding the numbers of bees alive each day. Samples of dead bees were checked for nosema disease.

We tested the following sugars:

High fructose corn syrup (ISOMEROSE 100 Brand High Fructose Corn Syrup; lot 22, Clinton Corn Processing Co., Inc. Clinton, IA 52732).

Grape syrup (white grape juice concentrate 68° Brix, sample TK 45, Delano Growers Co-op Winery, Delano, CA 93215).

Sucrose (C and H Brand table sugar from a grocer).

Honey (unfiltered, unhealed from mixed flora at Tucson, AZ, less than 1 year old).

Water was added to give syrups with refractometer readings of 50 %. (This is 50 % u/v for sucrose, but about 52 % for the other sugars.) The syrups were fed from inverted jars with perforated lids. Water was supplied separately although very little was taken. Both jars rested on the parallel wood bars that supported combs. Fresh, weighed jars of syrups were supplied daily, and consumption was measured by changes in weight of the jars. Jars held without bees had very low weight loss so corrections were not necessary for a blank.

Data were recorded for number of dead bees each day, weight of syrup removed each day, weight of wax produced, weight of syrup (honey?) stored in new comb, number of cells and number of sealed cells of honey comb, and size of cells. The data were subjected to analysis of variance. Where a significant difference was shown by an F test, a Student-

Neuman-Keuls multiple range test was used to establish which treatments differed from one another.

Sugars in the syrups and in capped honey from combs were identified by two-dimensional thin-layer chromatography. After diluting with water 1 to 100, 1 to 3 *u*l aliquots were spotted onto silica gel G plates. These were developped twice in one direction with n-butanol - acetonc - water (4:5:1) and twice in the perpendicular direction with phenol-water (3:1) and then stained with Saini's p-aminobenzoic acid reagent for qualitative identification (BARKER and LEHNER, 1974 d).

Comb wax was dissolved in benzene (40 *u*g/*u*l), and 1-2 *u*l were spotted onto a plate of silica gel G. These plates were developed in benzene and charred at 120 °C with fresh 40% sulfuric acid in ethanol to identify classes of lipids.

**RESULTS**

Differences between tests in the number of bees per cage were not significant. In all cages fed grape syrups, bees soon developed dysentery. The checks for nosema disease were negative except for a few bees fed honey; these had less than 15 spores per bee. Thus, disease was not a problem.

Survival was longest on sucrose syrup, and the difference was significant. Survival on grape syrup was reduced significantly. The difference between honey and high fructose corn was non-significant (Table 1).

Consumption per bee day, wax production per bee day, ratios of honey stored to syrup consumed, number of capped cells of honey, and ratio of wax produced to syrup consumed were all significantly less for bees fed grape syrup. The differences between honey, sucrose, and high fructose corn syrup were not statistically significant for any of these measurements (Table 1).

TABLE 1. - *Summary of results (means ± SD).*
Data underlined by the same line do not differ at 5 % probability level.

| Measurement | Sucrose | Honey | High Fructose Corn Syrup | Grape Syrup |
|---|---|---|---|---|
| LT50 (days) | 56.3 ± 8.1 | 31.3 ± 2.5 | 37.7 ± 2.1 | 13.3 ± 1.2 |
| mg. consumption/bee day | 59.0 ± 6.9 | 66.3 ± 13.7 | 60.1 ± 3.2 | 31.8 ± 8.1 |
| mg. honey/bee day | 10.4 ± 1.4 | 13.4 ± 5.8 | 10.3 ± 1.2 | .6 ± .7 |
| mg. wax/bee day | .73 ± .10 | .73 ± .15 | .69 ± .05 | .23 ± .08 |
| honey/syrup | .177 ± .017 | .195 ± .045 | .171 ± .013 | .016 ± .016 |
| wax/syrup | .012 ± .006 | .011 ± 0 | .011 ± .007 | .008 ± .007 |
| capped cells | 538 ± 477 | 75 ± 39 | 94 ± 45 | 0 |

---

The following sugars were detected:

Grape syrup: glucose, fructose only - no trace of other sugars.
High fructose corn syrup: fructose, glucose, faint traces of sucrose, and a faint trace of unknown with an R(f) near melezitose.
Honey: fructose, glucose, and traces of sucrose and maltose.
"Honey" from grape syrup: insufficient available.
"Honey" from high fructose corn syrup glucose and fructose with traces of maltose and unknown (melezitose?).
"Honey" from honey: fructose, glucose, sucrose, and maltose with traces of melezitose and raffinose.
"Honey" from sucrose: fructose, glucose, and sucrose with traces of maltose and melezitose.

Waxes from the different syrups showed no obvious qualitative differences with preliminary chromatographic analyses.

Cell diameter and wall thickness did not differ significantly when measured under calibrated binoculars. The wall thicknesses were highly variable.

**DISCUSSION AND CONCLUSION**

We had suspected that grape syrup contained toxic galactosides because galactosides cause dysentery and are common constituents of plant juices. However, chromatography failed to confirm this. The manufacturer suggested that sulfur dioxide might be the toxin. Nevertheless, a different sample that was low in sulfur dioxide was also toxic.

The survival data agree with our earlier reports that no sugar sustains bees better than sucrose.

*Received in October 1977.*

**ACKNOWLEDGMENT**

Stephen TABER III of ARS, USDA gave helpful advice on beekeeping. Technical assistance by Michael KUNZMANN is appreciated. Dr. Richard E. DAEHLER, Clinton Corn Processing Co., supplied Isomerose-100 Brand High Fructose Corn Syrup and information on its sugar composition. Harold ROLAND, Delano Growers Co-op Winery, supplied grape syrup.

The use of a trademark does not constitute an endorsement of a product by the USDA.

**ZUSAMMENFASSUNG**

EIN LABORVERGLEICH VON STARK FRUKTOSEHALTIGEM MAISSIRUP.
TRAUBENSIRUP. HONIG UND ROHRZUCKERSIRUP ALS ERHALTUNGSFUTTER FUR GEKAFIGTE HONIGBIENEN

Die gekafigten Honigbienenvolker verzehrten weniger Traubensirup als Rohrzuckersirup, Honig oder stark fruktosehaltigen Maissirup. Die mit Rohrzuckersirup gefutterten Bienen lebten am langsten. Traubensirup rief schwere Ruhr hervor und verminderte die Lebensdauer. Die mit Traubenzucker gefutterten Bienen erzeugten weniger Honig und weniger Wachs.

Im Traubensirup wurden keine giftigen Galaktoside gefunden. Die giftige, Ruhr erzeugende Substanz bleibt unbestimmt.

**RESUME**

ETUDE COMPARATIVE AU LABORATOIRE DU SIROP DE MAIS A FORTE TENEUR EN FRUCTOSE, DU SIROP DE RAISIN, DU MIEL ET DU SIROP DE SACCHAROSE COMME PRODUIT DE NOURRISSEMENT POUR ABEILLES ENCAGEES.

Les colonies d'abeilles encagees ont consomme moins de sirop de raisin que de sirop de saccharose, de miel ou de sirop de mais a forte teneur en fructose. Les abeilles nourries au sirop de saccharose ont vecu plus longtemps, tandis que le sirop de raisin a diminue la longevite. Les abeilles nourries au sirop de raisin ont egalement produit moins de miel et moins de cire.

Aucun galactoside toxique n'a ete mis en evidence dans le sirop de raisin; la substance toxique qui cause une forte dysenterie n'a pas **ete** identifiee.

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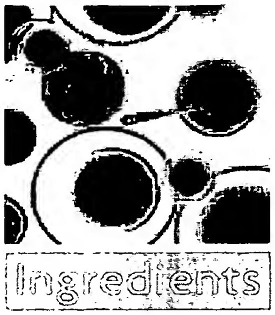


# The Use of Nutritive Sweeteners in Organic Food Processing Operations

By Cheryl R. Mitchell, Ph.D.

Nutritive sweeteners are the backbone of most food formulations, from baked goods to beverages. They are responsible for the bulk of the food product and usually are the first or second ingredient listed on the label. As such, the choice in sweetener affects not only the taste, appearance and functionality of the product, but also the successful manufacturing and marketing of the product. The growing organic industry has caused an increase in production of more and more diversified organic sweetener ingredient products to meet the needs of organic food product manufacturers. During the past 20 years, a variety of organic sweetener ingredient products have become available on an industrial scale. However, in order to select the right sweetener, it is important to have an understanding of the availability, composition and metabolic benefits of these sweetener ingredient products.

When considering the availability of organic sweeteners, it is essential to understand the source, supplier and pricing. The composition of the sweetener dictates the form of the sweetener (liquid or solid), as well as the functionality and consequently, the performance of the sweetener in imparting sweetness, flavor, mouthfeel and texture in the product. The metabolic benefit of the sweetener is dictated by both sweetener composition and source. For example, products that are designed for providing long-term energy, or that are well tolerated by diabetics, would utilize sweeteners having a different composition than those products providing quick energy. Products that are designed for specialty markets, such as infants, elderly or allergen-sensitive consumers, would pay special attention to the source of the sweetener. These features of availability, composition, and metabolic benefits affecti the success of both the manufacturing and marketing of the final organic product.

## Availability

Nutritive organic sweeteners that are commercially available in industrial quantities include agave, barley malt, cane, cane invert, cane brown sugar, corn, honey, juice concentrates, maple, molasses, oat, rice, tapioca and wheat (see box, Website Sweet Spots). Important factors in the availability of these sweeteners include source of the raw material, supplier and pricing. Since large-scale production of organic products requires at least pallet loads of sweetener ingredient, only those organic sweeteners that are sold in minimum pallet load quantities of either 50-lb. bags, 55-gal. drums or bulk tankers are considered here. The source of the starting material is a critical consideration for certain target markets. For example, sweeteners from tapioca or rice are preferred for developing hypoallergenic or infant products due to their low allergen characteristics and ease of digestibility.

Domestically manufactured sweetener ingredients allow for stability in supply. Sweetener products manufactured in the U.S.

| Source | Available Forms: Syrup | Available Forms: Solids | Taste |
|---|---|---|---|
| Barley Malt | X | X | Distinct |
| Corn | X | X | Neutral |
| Oat | X | X | Distinct |
| Rice, Brown & White | X | X | Distinct |
| Tapioca | X | X | Neutral |
| Wheat | X | X | Neutral |

Table 1. Industrial organic sweeteners derived from the hydrolysis of starch.

do not risk import problems and are more adaptable to supplying customer needs. Importantly, technical assistance with regard to quality and versatility of the sweetener ingredient are more directly available and can be a significant advantage in product development. Additionally, it is possible to obtain liquid sweetener in bulk tanker loads rather than in drums or totes. Depend-ing on production size, the savings on packaging alone could be significant.

Consistent and reproducible sweetener ingredient quality is a function of the supplier. Product specifications giving ranges in sugar composition, taste, flavor, color, nutritional and microbial analysis should be provided by the supplier of choice. Choosing suppliers that have strong technical services, including product development assistance, can more readily assist in helping the customer select the right sweetener for the product.

Pricing is dependent upon the amount purchased or contracted. Stable and consistent purchase and supply agreements benefit both parties. All products are subject to fluctuations in raw material pricing. However, in the case of starch hydrolyzed sweeteners and cane products, the prices remain fairly stable because of worldwide commercialization of the crops in the organic and non-organic domain. Typically, for truckload quantities, starch hydrolyzed products range from about $0.85 per pound to about $1.50 per pound. Tapioca syrups are on the lower end and oat syrups are on the higher end of the pricing scale. Other sweeteners such as agave, fruit juice concentrates, honey or maple, are more subject to limitations in supply and tend to be on the order of pricing from $1.00 to as high as $2.00 per pound. Evaporated cane juice or related products such as brown sugar, invert cane juice or molasses are the least expensive of the organic sweeteners and tend to be in the $0.45 to $0.70 per pound range.

Table 2. Carbohydrate composition of organic starch hydrolysis sweeteners.

| Type of Conversion[1] | Dextrose Equivalent (DE) | Carbohydrate Profile[2]: % Fructose | % Glucose | % Maltose | % Complex Carbohydrate | Sweetness Intensity[3]: Syrup | Sweetness Intensity[3]: Solids |
|---|---|---|---|---|---|---|---|
| Low | 20-40 | <1 | 2-15 | 6-30 | 55-90 | 0.10-0.20 | 0.10-0.25 |
| Maltose | 40-60 | <5 | 3-10 | 30-70 | 20-65 | 0.15-0.45 | 0.15-0.55 |
| Medium | 30-60 | 0 | 10-40 | 20-35 | 25-65 | 0.20-0.50 | 0.20-0.60 |
| High | 60-95 | 0 | 35-95 | 35-50 | <10 | 0.45-0.60 | 0.55-0.75 |
| Fructose | N/A | 10-30 | 30-90 | 30-45 | 0-20 | 0.35-0.80 | N/A |

[1] General categories and guidelines. Actual syrups may differ.
[2] Relative percent by weight of carbohydrate. Values are approximate; degree of conversion (splitting of starch chains) varies among suppliers and products.
[3] Relative to 1.0 for granular sucrose, calculated from typical sugar content.

## Composition

In addition to availability of flavoring agent, it is important to choose a sweetener based on the carbohydrate profile. The carbohydrate profile of a sweetener describes the distribution of simple and complex cabohydrates. Simple carbohdyrates or "sugars" as defined on the Nutritional Facts panel of food labels include predominantly one or a combination of glucose, fructose, maltose or sucrose. Complex carbohydrates, such as maltodextrin, are listed as "other carbohydrate" in the Nutritional Facts panel.

There are two broad category of sweeteners: those derived from the hydrolysis of starch, and those that are not. Starch hydrolyzed products are those sweeteners that are derived from the storage carbohydrates found in barley, corn, oat, rice, tapioca and wheat (Table 1). Starch is a carbohydrate molecule that is based upon chains of glucose. Hydrolysis of these chains using natural enzymes yields different quantities of glucose, maltose and complex carbohydrates. Typical carbohydrate profiles that result from starch hydrolysis are given in Table 2. The composition of sugars and complex carbohydrates in sweeteners resulting from starch hydrolysis can be controlled by the ingredient manufacturer to produce a variety of syrups with considerable differences in functionality and applications.

The other general category of sweeteners ingredients are those derived by concentrating (and sometimes hydrolyzing) the sap, fruit juice or nectar of plants. The storage carbohydrate in agave is inulin, which is a carbohydrate based on polymers (or chains of fructose). Hydrolysis of this product produces a sweetener composition of predominantly fructose with very little complex carbohdyrates. The composition of products such as honey, cane juice, fruit juice concentrates or maple syrup for the most part include only simple carbohydrates in the form of glucose, fructose or sucrose (Table 3). The sucrose in cane sugar can be hydrolyzed to fructose and glucose and is referred to as an invert cane juice.

The carbohydrate profile has an obvious affect on sweetness intensity. On a scale of 0 to 1, if granular sucrose is taken at 1, the sweetness intensity of the dry forms of other complex and simple carbohydrates are: maltodextrin (0.15), maltose (0.35), glucose (0.65) and fructose (1.25). The combination of these carbohydrates result in proportional differences in sweetness intensity. Sweetness intensity is directly related to the total carbohydrate content of the sweetener. A comparison of a syrup or solid form of a specific sweetener ingredient shows that the syrup, which contains a higher moisture content, has less total sugars

## Sweet Success with Organic Tapioca

Tapioca is the newest addition to commercially available organic sweeteners. At a time when both corn and rice sources in the U.S. are plagued with genetically modified organism (GMO) and pesticide issues, tapioca is providing a fresh and guaranteed organic food ingredient source to industry processors. Organic tapioca sweetners offer manufacturers several advantages in product formulation, including digestibility, hypoallergenicity, low color, neutral flavor, accentuated sweetness and ease of processing. These sweeteners result from the natural enzymatic hydrolysis of organic tapioca starch, which is isolated from the tuberous root of the manioc plant—also known as the mandioca, yucca, cassava or tapioca—that grows predominantly in equatorial climates. The tapioca starch source is non-GMO and is traditionally a low input culture.

The composition of tapioca starch is different from other starches in three distinct ways. First, tapioca starch contains less protein and lipids. As such, all of the sweetener products resulting from the hydrolysis of tapioca starch are low in color and have a neutral taste. The neutral taste is essential for products that have a delicate flavor profile such as natural fruit flavors and vanilla. Additionally, the absence of any distinct competing flavor in the organic tapioca sweetener accentuates the sweetness of the tapioca syrup.

The second special feature of tapioca sweeteners is the fact that they are considered hypoallergenic. The ease of digestibility of the tapioca carbohydrates has routinely made it one of the top sweetener choice for infant and medical foods.

The third distinct quality of tapioca sweeteners is that tapioca starch is high in amylose, which is a special complex carbohydrate that results in lower-viscosity syrups. This is critical for those organic sweetener products that are high in complex carbohydrates (low conversion syrups). Low conversion syrups from other starch sources are so viscous that they are virtually impossible to work with on an industrial basis. Low conversion tapioca syrups, on the other hand, do not have a high viscosity and are readily pumped without the need to first heat the syrup. The absence of protein and lipids, coupled with the special carbohydrate, result in tapioca syrups that are easily filtered through a 0.45-micron filter, producing a clear product with a high degree of microbiological stability.

A variety of functional organic tapioca syrups are now being made in the U.S. to meet the demands of the organic food manufacturers. Low-, medium- and high-conversion and maltose syrups, including those that contain fructose, are some of the specialty products that are now offered. A brief description of some of the typical sugar profile and composition of these organic tapioca syrups are given in the Figure 1. It is notable that the low con-

| | Grams/100 g |
|---|---|
| Total Solids | 78 |
| Moisture | 22 |
| Ash* | ‹0.2 |
| Fat | ‹0.2 |
| Protein | ‹0.1 |
| Carbohydrate | 77.5 |

| Relative % | Dextroxe Equivalent | Fructose | Glucose | Maltose | Complex Carbohydrates |
|---|---|---|---|---|---|
| Low Conversion | 27 | 0 | 5 | 13 | 82 |
| Low Conversion | 40 | 0 | 10 | 18 | 72 |
| Maltose | 42 | 0 | 5 | 35 | 60 |
| Medium Conversion | 69 | 0 | 35 | 50 | 15 |
| High Conversion/Fructose | 74 | 10 | 35 | 35 | 20 |

*Sodium, 40 mg; Potassium, 18 mg; Calcium, 7 mg; Magnesium, 3.4 mg; Phosphorus, 2.5 mg

Source: Ciranda, Inc., 2003

Figure 1. Composition of tapioca syrups.

and consequently, a lower sweetness intensity, than its solid counterpart.

The carbohydrate profile also affects the form of the product. The form of the product is critical for manufacturing. Many manufacturers cannot readily handle liquid products and vice versa with regard to solids. Consequently, if the final product is a liquid, a syrup form of the sweetener ingredient, which is usually less expensive, would be more economical and better suited for manufacturing. All forms of sweeteners are initially processed in the liquid state. If a dry form is not necessary, purchasing the liquid form can be considerably more economical. In general, sweetener ingredients containing fructose or larger concentrations of glucose and maltose are more difficult to dry and are not always available as a dry product.

Sweeteners also may contain molecules other than carbohydrates, including protein, fats and minerals. All of these affect the flavor of the sweetener ingredient to some degree. Some flavors are characteristic and desirable in food product formulations. However, in manufacturing products with desired target flavors such as vanilla or strawberry, the natural flavor of the sweetener may become overwhelming. In general, starch hydrolysis products made from the separated starch rather than the whole grain have a more neutral flavor associated with the sweetener. Other sweeteners, like evaporated cane or fruit juice, which are refined by crystallization, filtration or further separation of the non-carb-ohydrate components, result in more neutral-tasting sweeteners.

Besides differences in sweetness, the carbohydrate profile of the sweetener ingredient results in different

| Type | %Fructose[1] | %Glucose[1] | %Sucrose[1] | Taste | Sweetness Intensity[2] | |
|---|---|---|---|---|---|---|
| | | | | | Syrup | Solids |
| Agave | 70 | 30 | 0 | Distinct | 0.9 | N/A |
| Brown Sugar | 0 | 0 | 90-96 | Distinct | N/A | 0.95 |
| Evaporated Cane Juice | 0 | 0 | 99 | Neutral | 0.7 | 0.9 |
| Evaporated Cane Juice, Invert[3] | 25-50 | 25-50 | 0-50 | Neutral | 0.8 | N/A |
| Honey | 55 | 43 | 2 | Distinct | 0.8 | N/A |
| Clarified Juice Concentrates | 48-62 | 20-48 | 4-5 | Distinct | 0.60-0.75 | N/A |
| Maple | 2-4 | 2-4 | 92-96 | Distinct | 0.8 | N/A |
| Molasses | 7-11 | 7-11 | 45-52 | Distinct | 0.5 | N/A |

[1] Relative percent by weight of total carbohydrate.
[2] Relative to 1.0 for granular sucrose; calculated from typical sugar content.
[3] Some suppliers offer a line of products with different levels of inversion.

Table 3. Typical properties of industrial organic sweeteners, other than starch-based.

functional properties of the sweetener ingredient. Humectancy, binding, mouthfeel, sweetness, osmolality, or freezing point depression are functions of different carbohydrates. For example, sweeteners containing just sucrose or only glucose tend to crystallize readily, and their use in confectionary products is well understood and utilized for this purpose. Fructose and maltose are very hygroscopic and add considerable humectancy to products. Maltodex-trins are much less hygroscopic, and in fact, are commonly used in combination with simple sugars to assist in the drying of glucose and fructose products. An example of this is powdered honey, which is a blend of maltodextrin and honey.

The carbohydrate profile also dictates the preferred usage or application of the sweetener ingredient. For example, high glucose syrups, which are predominantly glucose, are used in the beverage industry because the sweetness is maximized and provides a characteristic mouthfeel. Maltose syrups are preferred in the bakery industry because of their humectant property. Maltose syrups also are desirable in the confectionary industry for their combined sweetness and ability to produce hard candy that is not sticky. Sucrose-containing sweeteners have a high sweetness impact, and crystallization properties that make them most useful in confectionary and bakery products. Low-conversion starch hydrolysates, which have relatively small amounts of glucose and therefore low osmolality, are used as fillers and bodying agents in many baked goods and beverages. The higher sweetness of syrups containing fructose makes them particularly desirable for beverages. The humectant property of syrups containing either fructose, or combinations of glucose and maltose is advantageous in bakery and extruded bar products.

## Metabolic Benefits

Metabolic benefits of a sweetener ingredient are an essential consideration for the marketing of the product. Organic products are being designed to meet specific target markets such as

infant, elderly, sport or special medical needs. The source and composition of the sweetener ingredient dictates these ingredient choices. Hypoallergenic sources include rice and tapioca. Maple, honey, molasses and rice contain significant quantities of minerals and proteins that, while affecting flavor, also provide magnesium and phosphate, which are metabolically advantageous for the digestibility of the carbohydrate.

The types of sugars used also affect digestibility and utilization. Glucose, maltose and maltodextrins are easily digested, but over different periods of time. Glucose, for example, provides a source of quick energy and is digested more rapidly than maltose or maltodextrins. The more complex carbohydrates are preferred for nutritional or diet products providing long-term energy.

### Website Sweet Spots

*Several websites offer pages or searchable databases listing suppliers of industrial organic sweeteners along with the products they supply.*

**Organic Trade Association Website Directory**
www.ota.com
The Organic Pages Online North American Resource Directory provides more than 1,300 product and service listings, with lists of organic ingredient suppliers.

**All Organic Links**
www.allorganiclinks.com
This site features hotlinks to 120 organic ingredient suppliers and manufacturers with helpful descriptions of the sweeteners and ingredients these companies offer.

**Food Navigator Database**
www.foodnavigator.com/ingredients
A good list of products and services suppliers includes an organic category that lists several sweetener suppliers.

From a diabetic point of view, glucose results in a rapid requirement for insulin and may not be desirable. More slowly digested carbohydrates such as maltose or maltodextrins are preferred. Fructose, while providing advantages in sweetness intensity, is metabolized differently than glucose, maltose or maltodextrins. Fructose is metabolized directly to fat, which is an undesirable metabolic property of fructose. However, the metabolic pathway of fructose does not require insulin and is therefore preferred by diabetics. Additionally, more and more people are being reported as fructose intolerant, which means that they cannot metabolize fructose at all and causes some additional digestive problems and toxicity.

### Hitting the Selection Sweet Spot

Choosing an organic sweetener is not a simple task. Once the type of product and the target market have been identified, the next step is to select a group of available sweeteners that will work in the selected product and market. Identifying the availability in terms of source and pricing, composition in terms of functionality, and required benefits will be the basis for this decision. Once the desired sweetener is chosen, research and development takes over to make the product. If the selection of the sweetener is a good one, the development, manufacturing and marketing of the product will be off to a good start. ■

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